

REMARKS

This paper is filed responsive to the Final Rejection mailed on May 14, 2010 in the above-identified matter. It is timely in view of the three month shortened statutory period for response. A Request for Continued Examination is respectfully submitted concurrently herewith. Applicants request reconsideration in light of the following remarks.

Claims 73-86 are pending in the application.

The Final Rejection of May 14, 2010 rejected claims 73-86 under 35 U.S.C. 103(a) as being unpatentable over Jin (CN166960A published 12/10/1997) in view of Meybeck et al. (US 5,034,228). The Final Rejection responded to applicants' previous arguments as follows:

Applicant should note that the claims are given its broadest claim interpretation. Jin teaches soy-protein powder in the amount of 2-5% as stated in the remarks, which meets the claim limitation of instant claim 86. The remark...that Jin does not teach the soybean isolate was not processed confirms the Examiner's position. If Jin fails to teach that the soybean extract was processed, one of ordinary skill in the art would reasonably expect that the soy protein isolate was not processed and therefore had not been denatured.

The argument that Jin's soy protein isolate is used for feed for animals is immaterial to the rejection of record what matters is that Jin specifically teach the use of soybean protein powder for treating the face by applying the composition as a mask, wherein after several application of the mask, the acne is obviously decreased...

Jin teaches using a composition comprising soybean protein powder for treating the face, wherein after several application of the mask, the acne is obviously decreased...Because Jin does not heat, etc. his soybean powder, it is therefore considered non-denatured...Inherently, the soy flour/powder will have trypsin-inhibiting activity because "products of identical chemical composition can not have mutually exclusive properties...and because Jin's product was not heated or processed, it is necessarily "not been denatured". [Final Rejection, pp. 4-5]

The Final Rejection further notes that the Seiberg Declaration is insufficient as the exhibits do not "teach what is being claimed." [Final Rejection, p. 7]

Applicants respectfully request reconsideration of the rejection set forth in the Final Rejection in view of the amendments to the claims and the ensuing discussion.

As previously noted, Jin relates to a "complex spirulina beauty masque powder" [Jin, p. 3] which contains the following materials:

Serial No. 10/659,598

The raw materials presented in the present invention are comprised of 20 to 40 grams of spirulina, 8 to 30 grams of pearl powder, 20 to 40 grams of pure pollen, 10 to 30 grams of mung bean flour, 5 to 12 grams of **soy protein isolate powder**, 8 to 12 grams of powdered silkworm larvae, 6 to 15 grams of bletilla tuber powder and 6 to 15 grams of talcum powder. [Jin, translation, p. 3] (emphasis added)

Applicants respectfully submit that Jin would not have suggested or described the compositions or methods of applicants' invention to one of ordinary skill in the art at the time the invention was made.

As applicants have indicated earlier in this prosecution, the compositions set forth in Jin indicate the presence of "soy protein isolate powder" as set forth above. As previously noted, applicants respectfully contend that those of ordinary skill in the art at the time the invention was made would have understood "soy protein isolate powder" to be used as feed for animals and humans. Soybean-derived materials that are acceptable for use for oral ingestion **must be denatured** in order to eliminate the presence of soy trypsin inhibitor. The presence of soy trypsin inhibitor in nutritional materials would cause serious gastrointestinal side effects to the individual ingesting such materials. Thus, applicants respectfully submit that one of ordinary skill in the art, reading Jin, would not have learned to utilize soybean extracts containing soy trypsin inhibitor.

Furthermore, in response to the Final Rejection's assertions, applicants respectfully submit that even if one of ordinary skill in the art would have assumed that soy protein isolate powder used in Jin had not been denatured, there is ample evidence in Jin itself that the materials would have been denatured in the process of making the compositions therein. Jin indeed subjects the powders and materials utilized in the compositions set forth therein to increased heat in order to "sterilize" the materials, as follows:

...The powder is the[n] sterilized with ethylene oxide. The method thereof being: the powders are added to the inside of a sterilizer, and the sterilizer is sealed and evacuated. **Ethylene oxide is heated to 50°C** and vaporized by a jacket heater, and then ethylene oxide gas is passed through the sterilizer at 50°C. **The jacket heater heat is maintained by 50°C water. After the materials have been sterilized for 2 to 7 hours**, the ethylene oxide gas in the sterilizer is stripped out by a vacuum pump, and then discharged into a pond. [Jin, translation, pp. 3-4] (emphasis added)

Thus, the soy protein isolate powder is exposed to Ethylene oxide (hereinafter, "ETO"), an agent known to act by protein denaturation. As set forth in the accompanying Declaration of

Miri Seiberg, and as summarized in the book "Validation of Pharmaceutical Processes: Sterile Products", Second Edition by Carleton (Hardcover - Nov. 5, 1998), p.367, section 3, sterilization by ETO is based on the chemical reactions between ETO and proteins, which modify the proteins so ...”their modifications by ETO will disrupt or destroy the protein’s activity”. [Carleton, p. 367, Declaration of Miri Seiberg, ¶1] Thus, one of ordinary skill in the art at the time the invention was made would have known that exposure of soy protein isolate powder to ETO, as set forth in the Jin publication, **would have caused the denaturation** of proteins existing in the soy protein isolate. In contrast, the compositions and methods of applicants’ invention aim to keep proteins active, while the sterilization by ETO, as in Jin, aims to destroy and inactivate proteins.

Furthermore, Jin clearly states that soy protein isolate powder should be subjected to elevated heat for several hours, which one of ordinary skill in the art would have known to cause substantial denaturation of the trypsin inhibitor proteins contained therein.

In addition, applicants respectfully submit that, in order to be relied upon as a “teaching” of failure to denature the soy protein isolate powder, Jin would have had to patently disclose this step. One cannot rely upon Jin for an affirmative teaching of such a disclosure if it fails to mention it at all. Applicants respectfully submit that Jin is deficient in several ways in directing one of ordinary skill in the art toward the compositions and methods of applicants’ invention.

Nor would Meybeck et al. compensate for the deficiencies of Jin in leading one of ordinary skill in the art toward the compositions and methods of applicants’ invention. As was noted in applicants’ earlier responses, Meybeck et al. would have taught one of ordinary skill in the art **away** from the compositions and methods of applicants’ invention. The Meybeck et al. patent relates to “hydrous lipidic lamellar phases or liposomes containing, as an active agent, a retinoid or a structural analogue of retinoid...These compositions are more efficient against acne and less irritant for the skin...” [Meybeck, et al., Abstract]. “Hydrogenated soya lecithin” [Meybeck, et al., col. 8, l. 2] is mentioned as one of the components of a composition for treating acne skin. However, applicants respectfully assert that Meybeck et al. neither suggests nor describes the compositions or methods of applicants’ invention.

Serial No. 10/659,598

Meybeck et al. utilizes lecithin in the liposomes described therein to form the lipidic layer portion of the liposomes. Soybeans have a multitude of components, which can be separated out from the natural beans in several ways. Generally, lecithin is extracted from the soybeans using organic solvents—these solvents solubilize the lipidic lecithin molecules and separate them from the remainder of the beans. Soy trypsin inhibitor proteins, like other proteins, are not soluble in organic solvents. Moreover, organic solvents tend to denature proteins. Meybeck et al. nowhere states or suggests that the soya lecithin useful in the liposomes described therein maintains soy trypsin inhibitory activity nor does it recognize that soy trypsin inhibitory activity is important in enhancing the activity of retinoids against acne. Applicants therefore respectfully submit that Meybeck et al., alone or in combination with Jin, would not have led one of ordinary skill in the art to the compositions and/or methods of applicants' invention.

In view of the foregoing, applicants respectfully request reconsideration of the rejection of claims 73-86 under 35 U.S.C. 103(a) set forth in the Final Rejection as being unpatentable over Jin (CN166960A published 12/10/1997) in view of Meybeck et al. (US 5,034,228). An early allowance is earnestly solicited.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby
Reg. No. 30,194
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
August 13, 2010